

Irradiator Technology H-315

Session 10

Good Manufacturing Practices

ISO 9001:2000



Section 1 General

- Canadian Irradiation Centre Quality System Manual
- Document and Data Control
 - Procedure format
 - Procedure numbering
 - Procedure revision
 - Procedure distribution
 - Notice of change
 - Obsolete procedures
 - Master list

Section 1 General

- Management's Responsibility
 - CIC organization chart
 - CIC Quality Policy Statement
 - Management review
- Contract Review
- Corrective and Preventive Action (CAR)
- Management Review

Section 2

Standard Operating Procedures

- Product reception
 - Receiving
 - Damaged products
 - Count discrepancy
- Special conditions
 - Temperature
- Product warehousing before and after irradiation

Section 2

Standard Operating Procedures

- Routine Product Irradiation
 - Instructions Sheet
 - Graphic on how to place the product inside the carrier
 - Graphic where to place the dosimeters (coordinates)
 - What is the cycle time?
 - Minimum and maximum dose required
 - Reference to the dose mapping file number for this product
 - Product load / unload count

Section 2

Standard Operating Procedures

- Product labeling, use of Go-No Go dots
- Routine Product dosimetry
 - Dosimetry log sheet
- Product release
 - Criteria for product release
 - Reconciliation
 - Machine charts: Cycle log
 - NorTRACK Report
 - Certificate of irradiation
 - Product history file

Section 2

Standard Operating Procedures

- Product Shipping
 - Weight confirmation
 - Damage during shipping

Section 3 Instrument Calibration

- Calibration personnel
- Spectrophotometer(s)
 - Routine spectrophotometer
 - Back-up spectrophotometer
 - NIST neutral density filters
 - Records
- Thickness gage(s)
 - Records

Section 3 Instrument Calibration

- Timers:
 - stopwatch
 - IR-147 timer
- Central Dose Rate
 - UC-15A and UC-15B
 - GC-220
 - GC-1000
- Scales

Section 4

Calibration of Dosimeters

- Harwell Red Perspex 4034 **(5-50kGy)**
- Harwell Amber Perspex 3042
- Harwell Gammachrome
- FWT-60 FILM
- FWT-90 FILM

Section 5

New Product Dosimetry

- Criteria for new dose mapping
- Handling of small samples
- IR-147 Irradiator Dose Mapping

Section 6

Product Testing

- Not applicable

Section 7

Maintenance Program

- Maintenance of instruments
 - Spectrophotometer, thickness gauges, timers,
 - Scales, irradiators, etc.
- Other
 - Pest control using approved methods
 - Fire extinguisher
 - Job Occupational Health & Safety considerations

Section 8

Customer Complaints

- Customer Complaint
 - Receiving and Recording complaints
 - Handling complaints
 - Investigation of complaints
 - Assessment and recommendations
 - Complaint closure
 - Complaint file contents
 - Analyzing
 - Trending
 - Reporting
 - File format

Section 9

Operational Audit

- Planning
- Audit Team
- Audit Frequency
- Duration
- Preparation for audit
- Conducting the audit
- Corrective action and Follow-ups
- Documentation and Record
- Reporting, Contents
- Evaluation

Section 10

Training

- Required Records
- Training needs:
 - Operator's helper
 - Radiation Safety Officer
 - Supervisor
 - Quality Assurance
 - Authorized licensed operator (irradiator) and ARW
- Consolidated training records
- Individual training records

Section 11

Access Control

- Key control, numbering
- Key distribution form
- Authorized Access to:
 - Office
 - Warehouse
 - Laboratory
 - Control room
 - IR-147 and PLC

Section 12

Process Deviation

- Process deviation description
- Signing authority
- Forms
- Action

Section 13

Quality Records

- Quality record's name
- Storage location
- Retention period

Section 14

Purchasing

- Purchasing procedures

Section 15

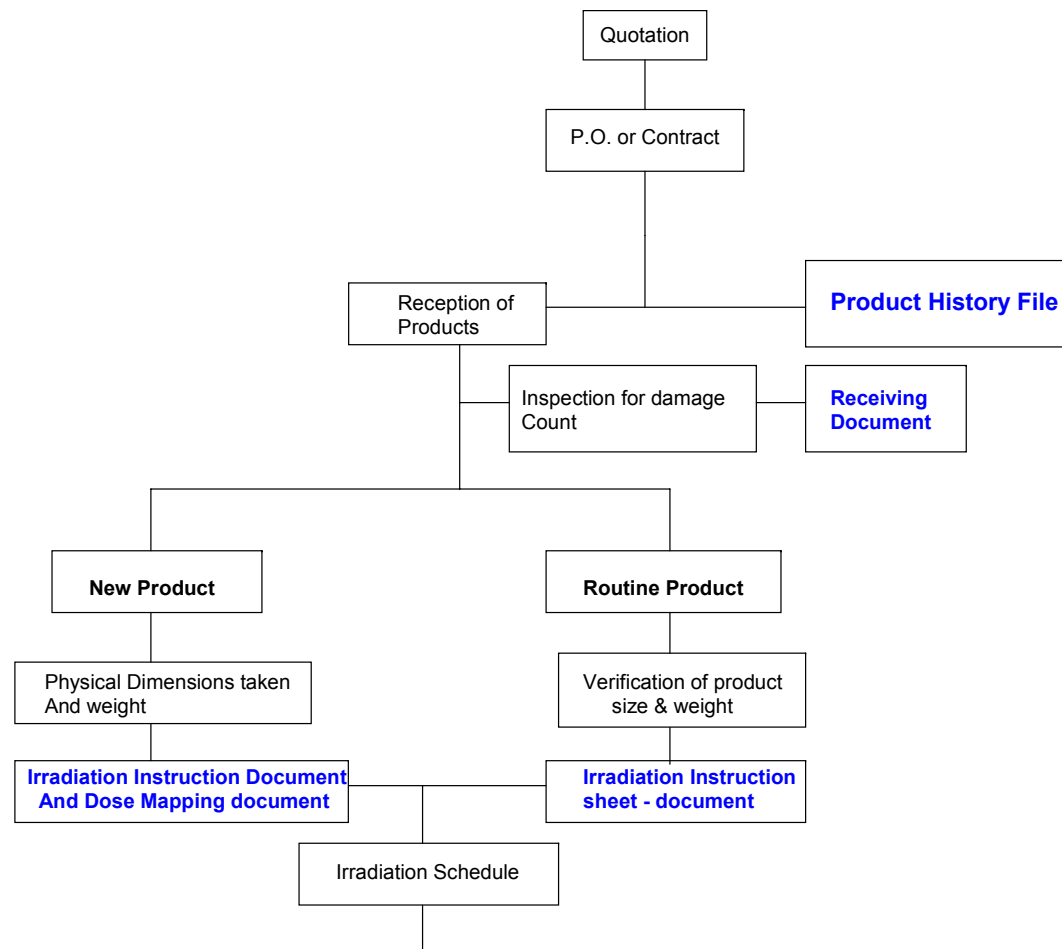
Statistical Techniques

- Statistical Techniques Procedures

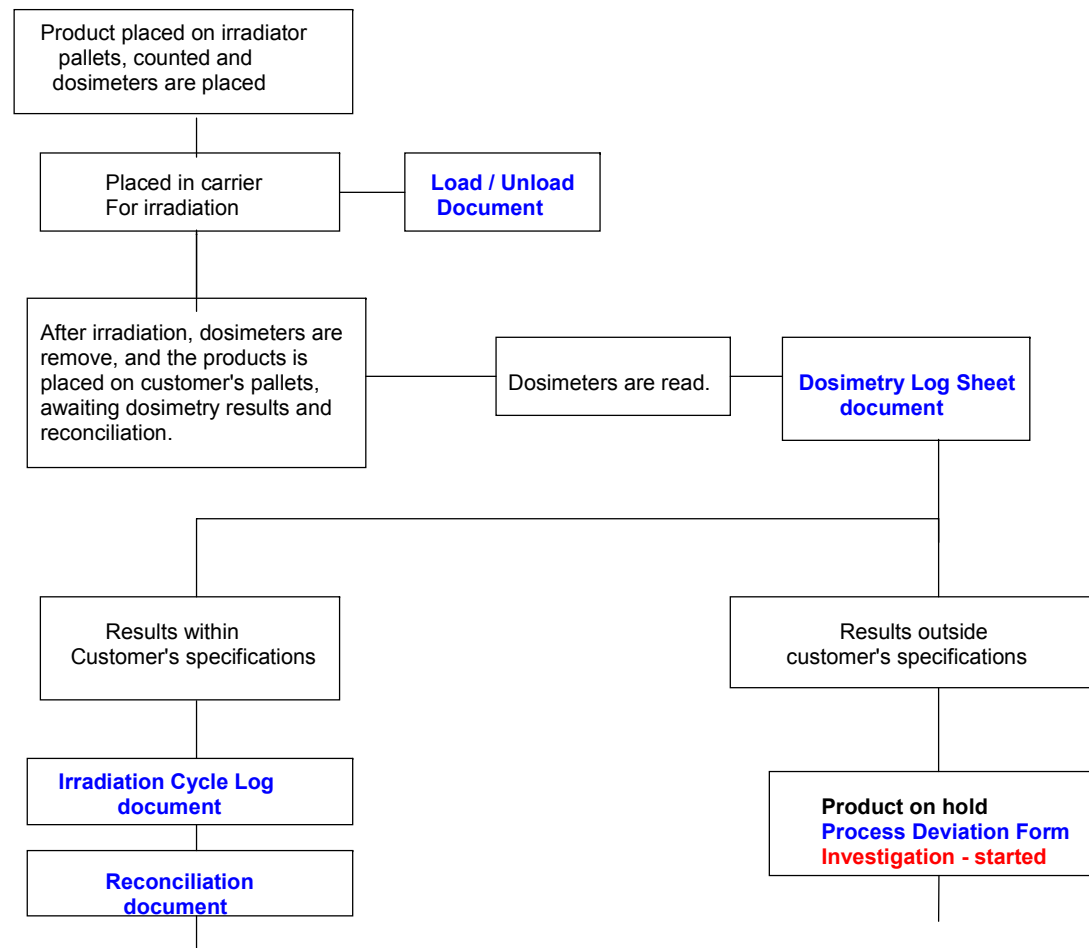
Appendices

- **Master Form List**
- **Master Procedure List**
- **Triggering calendar list**

Product Flow Diagram



Product Flow Diagram



Product Flow Diagram

